DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-315/S-009

Roxane Laboratories
P.O. Box 16532
Columbus, Ohio 43216-653

Attention: Ann M. Maloney
Director, Drug Regulatory Affairs-Approved Products

Dear Ms. Maloney:

Please refer to your supplemental new drug application dated April 6, 2001, received April 9, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Orlaam (levomethadyl acetate hydrochloride oral solution).

We acknowledge the May 3, 2001, teleconference and your May 9, 2001, correspondence confirming acceptance of the revised package insert.

This supplemental new drug application provides for a revised package insert to reflect the agreed upon changes from the March 30, 2001, approval letter for supplement S-006 and changes to comply with the changes to the regulations for 21 CFR Part 291 and 42 CFR Part 8.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert submitted May 9, 2001). Accordingly, the supplemental application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Sara Shepherd, Regulatory Project Manager, at (301) 827-7430.

Sincerely,

{See appended electronic signature page}

Cynthia McCormick, M.D.
Director
Division of Anesthetic, Critical Care,
and Addiction Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research